



Press Release, February 6, 2022

Diamyd Medical proceeds with initiation of Type 1 Diabetes Phase III trial in Europe

Diamyd Medical proceeds with the initiation of the Phase III trial DIAGNODE-3 in Europe with the Diamyd® diabetes vaccine. Results from in-depth analyses of the manufacturing process have shown no risk associated with a previously suspected contamination. The first patients are expected to be screened in March.

“We are extremely happy and relieved to proceed with the initiation of DIAGNODE-3 and I highly commend the team on their diligent efforts,” says Ulf Hannelius, CEO of Diamyd Medical. “We are now continuing at full speed and expect to screen the first patients in DIAGNODE-3 next month.”

As announced on November 30, Diamyd Medical paused the initiation of the Phase III trial DIAGNODE-3 while investigating a potential contamination in the manufacturing process of the active ingredient used in the study drug Diamyd®. In-depth analyses have now shown no risk associated with the potential contamination and the Company thereby proceeds with initiating DIAGNODE-3 in Europe where approvals have been received by Competent Authorities and Ethical Review Boards in the Czech Republic, the Netherlands, Spain, Poland and Sweden.

Work is ongoing to resolve the questions from the FDA with the aim of being able to include US clinics in DIAGNODE-3. Updates regarding these activities will be given by Diamyd Medical over the coming months.

About Diamyd Medical

Diamyd Medical develops precision medicine therapies for type 1 diabetes. The diabetes vaccine Diamyd® is an antigen-specific immunotherapy for the preservation of endogenous insulin production. Significant results have been shown in a large genetically predefined patient group in a large-scale meta-analysis as well as in the Company’s European Phase IIb trial DIAGNODE-2, where the diabetes vaccine was administered directly into a lymph node in children and young adults with recently diagnosed type 1 diabetes. Preparations for a confirmatory Phase III trial are on-going. A vaccine manufacturing facility is being set up in Umeå for the manufacture of recombinant GAD65, the active ingredient in the therapeutic diabetes vaccine Diamyd®. Diamyd Medical also develops the GABA-based investigational drug Remygen® as a therapy for regeneration of endogenous insulin production and to improve hormonal response to hypoglycaemia. An investigator-initiated Remygen® trial in individuals living with type 1 diabetes for more than five years is ongoing at Uppsala University Hospital. Diamyd Medical is one of the major shareholders in the stem cell company NextCell Pharma AB as well as in the artificial intelligence company MainlyAI AB.

Diamyd Medical’s B-share is traded on Nasdaq First North Growth Market under the ticker DMYD B. FNCA Sweden AB is the Company’s Certified Adviser; phone: +46 8-528 00 399, e-mail: info@fnca.se

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